CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-702/S-035

Trade Name: Lipitor

Generic Name: (atorvastatin calcium)

Sponsor: Pfizer, Inc.

Approval Date: July 2, 2002

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APPLICATION NUMBER:

20-702/S-035

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Reviews / Information Included in this NDA Review.

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Administrative/Correspondence Document(s)	X

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APPLICATION NUMBER:

20-702/S-035

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-702/S-035

Pfizer Ireland Pharmaceuticals
Attention: Christopher A. Graham
Director, Worldwide Regulatory Strategy
235 East 42nd Street, 150/7/12
New York, NY 10017

Dear Mr. Graham:

Please refer to your supplemental new drug application dated May 14, 2002, received May 15, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lipitor (atorvastatin calcium) tablets.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of an / drug substance atorvastatin calcium.

We have completed the review of this supplemental application, and it is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Margaret Simoneau, R.Ph., Regulatory Project Manager, at (301) 827-6411.

Sincerely,

{See appended electronic signature page}

Stephen K. Moore, Ph.D.
Chemistry Team Leader I, DNDC II for the
Division of Metabolic and Endocrine Drug Products,
(HFD-510)
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Stephen Moore
7/2/02 04:59:57 PM

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APPLICATION NUMBER:

20-702/S-035

CHEMISTRY REVIEW(S)

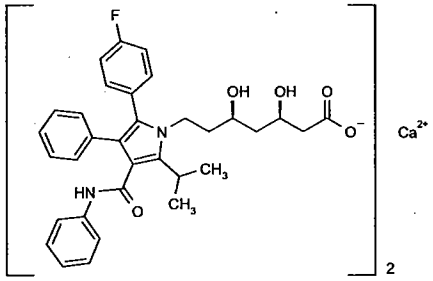
CHEMIST'S REVIEW

1. Organization CDE/HFD-510 Division Of Metabolism And Endocrine Drug Products	**2. NDA #** 20-702 Approved: 17-Dec-1996
3. Name and Address of Applicant Pfizer Ireland Pharmaceuticals[1] Pottery Road Dun Laoghaire County Dublin Ireland	**4. Supplement** SCS-035 Doc. 14-MAY-2002 Rec.15-MAY-2002 **5. Name of the Drug** Lipitor Tablets **6. Nonproprietary Name** Atorvastatin Calcium
7. Supplement provides for the addition of an atorvastatin calcium.	**8. Amendment** --

9. Pharmacological Category Lipid Modifier. HMG-CoA reductase inhibitor/ Antihyperlipoproteinemic agent.	**10. How Dispensed** Rx	**11. Related** -N. A.-
12. Dosage Form Tablet	**13. Potency** 10-, 20-, 40- and 80-mg	

14. Chemical Name and Structure
Atorvastatin Calcium

$(C_{33}H_{34}FN_2O_5)_2Ca$
FW = 2 x 557.7 + 40.0 = 1155.38 (anhydrous calcium salt)
CAS 134523-03-8
CAS 134523-00-5 (atorvastatin)
FW free acid $C_{33}H_{34}FN_2O_5$ = 558.66
FW calcium salt trihydrate $(C_{33}H_{34}FN_2O_5)_2Ca \cdot 3H_2O$ = 1209.42



[*R*-(*R**,*R**)]-2-(4-flourophenyl)-ß,-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-1*H*-pyrrole-1-heptanoic acid calcium salt (2:1)

15. Comments: This Changes Being Effected 30 Days Supplement provides an

16. Conclusions and Recommendations: The proposed

From the chemistry viewpoint this supplement can be approved.

17. Reviewer Name (and Signature) **Date Completed:** 06-JUN-2002

Xavier Ysern, PhD

R/D Initialed by

Stephen Moore, PhD
Chemist Team Leader **filename:** /nda/20702s35.doc

SS-CBE-30d AP

[1] **Authorized USA Agent:** Pfizer Inc., 235 East 42nd Street, 2800 Plymouth Road, New York, NY 10017 phone: (212) 733-4394

1 Page(s) Withheld

X § 552(b)(4) Trade Secret / Confidential

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Chemistry- 20-702
5035

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/s/

Xavier Ysern
6/24/02 02:13:49 PM
CHEMIST

Stephen Moore
7/1/02 01:30:49 PM
CHEMIST

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APPLICATION NUMBER:

20-702/S-035

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-702/S-035

CBE-30 SUPPLEMENT

Pfizer, Inc., Agent for Pfizer Ireland Pharmaceuticals
Attention: Rita A. Wittich
Vice President, Worldwide Regulatory Strategy
235 East 42nd Street 150/7/12
New York, NY 10017

Dear Ms.Wittich:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product:	Lipitor (Atorvastatin Calcium) Tablets
NDA Number:	20-702
Supplement Number:	S-035
Date of Supplement:	May 14, 2002
Date of Receipt:	May 15, 2002

This supplemental application, submitted as a "Supplement - Changes Being Effected in 30 days" supplement, proposes to add an ✓ ✓ of atorvastatin calcium.

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on July 14, 2002 in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be November 15, 2002.

Please cite the application number listed above at the top of the first page of any communications concerning this application. All communications concerning this supplemental application should be addressed as follows:

U.S. Postal Service/Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research

Division of Metabolic and Endocrine Drug Products, HFD-510
Attention: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857

If you have any questions, call me at (301) 827-6411.

Sincerely,

{See appended electronic signature page}

Margaret Simoneau, R.Ph.
Regulatory Project Manager
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

Margaret Simoneau
5/28/02 01:40:08 PM